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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,415	07/19/2000	LESA J. BEAMER	11034US02/0	2291

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EXAMINER
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MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/29/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/446,415

Applicant(s)

Beamer et al.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10/24/01 and 5/6/02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above, claim(s) 7-14, 24, and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 15-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-25 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jul 19, 2000 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

Applicants' arguments, filed 10/24/01 and 5/6/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### **SEQUENCE RULE NON-COMPLIANCE**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). See, for example, separately prepared oligonucleotide sequences in the last 3 lines of page 43. However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because these sequences lack SEQ ID NOs. therewith. Also, if these sequences are not in the present computer readable form sequence listing, then a new computer readable form sequence listing, a paper copy for the specification, a statement under 37 CFR § 1.821(f) and (g) are required which includes these sequences. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

**PRIORITY CLAIM INCOMPLETE**

If applicants desire priority under 35 U.S.C. § 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. The status of non-provisional application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

**VAGUENESS AND INDEFINITENESS**

Claims 1-6, 15, and 22 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is vague and indefinite in citing Figures 2-20 whereas only figures 1A through 6 are in the instant file. Where are Figures 7-20? Although applicants argue that claim 22 has been amended to correct this unclarity. Such an amendment has not been submitted.

Claims 1-6 and 15 provide for the use of atomic coordinates of BPI etc., for modeling, but, since the claim does not set

forth any actual steps involved, it is unclear what applicants are intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Applicants argue that the legal decision of Ex parte Gunter Bouillon supports the instant claim wording. In response the fact pattern of Ex parte Gunter Bouillon is very different from that in the instant claims. In claim 21, for example, under appeal regarding a 101 rejection there is clear wording of a physical applying of cleansing agent to skin. Thus, two items, a cleansing agent and skin are brought together in said applying step. No such physical bringing together or applying is present in instant claims 1-6. Thus, applicants' argument on this basis is non-persuasive due to the clearly different fact patterns as noted above. Claim 15 is added to this rejection as it only defines atomic coordinates but also lacks a step as in claims 1-3 from which it depends.

**USE CLAIMS REJECTED UNDER 35 U.S.C. § 101**

Claims 1-6 and 15 are rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. § 101. See the above response to arguments on this issue which are reiterated here as being equally non-

persuasive. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

**NON-STATUTORY SUBJECT MATTER UNDER 35 U.S.C. § 101**

Claims 1-6 and 15-23 are rejected under 35 U.S.C. § 101 because the claims are directed to non-statutory subject matter. Utilizing the general guidance for computer related inventions as summarized in the MPEP at section 2106 the first inquiry is directed to what applicants have invented or seek to patent. In the instant application the three-dimensional structure (non-functional descriptive material) of BPI for modeling purposes appears to be the basis for the invention. Then in the MPEP at section 2106, part II, subpart A, the inquiry is directed to what the invention as a whole accomplishes and notes that a useful, concrete, and tangible result is required. It is noted that instant claims 1-6 and 15-23 fail to cite any limitation that is either concrete or tangible, albeit potentially useful in drug design. Thus, instant claims 1-6 and 15-23 fail in two of the three criteria for statutory subject matter, wherein the statutory requirement therein requires all three criteria to be met. As guided in the MPEP at section 2106, part II, subpart B, a review of the disclosure and specific embodiments has failed to reveal concrete and tangible results for the instant invention. It is noted that fragments and variants are discussed in the

latter portion of the discussion in the specification with speculation as to possible usage results, but without proceeding beyond BPI data manipulation to obtain either a concrete or tangible result. As then guided in the MPEP at section 2106, part II, subpart C, a review of instant claims 1-6 and 15-23 also has failed to reveal any concrete and/or tangible result. Focusing on claim 1, for example, reveals modeling of BPI or fragments etc. which is deemed manipulation of abstract ideas in the form of atomic coordinates of BPI. Such abstract data manipulation also fails to produce any concrete and/or tangible result. In summary the instant invention as claimed in claims 1-6 and 15-23 are directed to non-statutory subject matter.

#### **SCOPE OF ENABLEMENT REJECTION**

Claims 1-6 and 16-23 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for practicing three dimensional modeling with the atomic coordinates in Table 4, does not reasonably provide enablement for any other BPI protein, fragment, analog, or variant without three-dimensional coordinates as in Table 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex

parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

It has been recognized that the crystallization of a protein in order to obtain suitable crystals for X-ray crystallography is a trial and error process. See Drenth at page 1, lines 1-20, where this trial and error aspect is discussed regarding a number of unknown factors in the crystallization process such as impurities, crystallization nuclei, etc. With several unknown factors and the acknowledgment that the crystallization process to obtain suitable crystals is the least understood step in X-ray structural analysis of a protein, it is reasonable to conclude that steps in this process lack enablement due to



unpredictability until atomic coordinates are produced of reasonably small resolution. Another publication indicating that certain crystals are of limited value due to low resolution is that of Benson et al. on page 644, second column, lines 1-6, of the section entitled "Structure determination". It is noted that the instant application only contains a single Table 4 listing of such atomic coordinates and that claims that are broader in scope beyond requiring the Table 4 coordinates lack enablement due to the unpredictability of making crystals in order to determine three-dimensional structures for modeling procedures.

#### **INFORMALITIES**

The disclosure is objected to because of the following informalities:

It is noted that the Figure designations on pages 14-15 of the specification differ from the actual Figures in that 1A is in the Figures whereas confusingly 1(A) is set forth on said page 14, for example. This has not been corrected in any submitted amendment.

Correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center

number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 26, 2002

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER